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### **REMARKS**

Before the amendment made herewith claims 71-74 were pending in the subject application. Claims 75-80 have been added herewith. Accordingly, after entry of the amendment made herewith, claims 71-80 will be pending.

#### **I. Regarding the amendments.**

Claim 73 has been amended to recite cells in suspension. Support for this recitation can be found in the specification, for example, at page 22, lines 11-19.

New claim 75 is directed to ex vivo cells. Support for this claim can be found in the specification, for example, at pages 38 to 54, which makes clear that the claimed cells are being introduced ex vivo. More specifically, page 48 to 51 discloses preparations of various cell lines, as currently claimed. These described preparations (e.g., heparanase added to BMSC cells, as described at page 48, lines 19-22) are clearly done ex vivo.

New claim 76 is directed to somatic cells. Support for this claim can be found in the specification, for example, at page 35, line 8, which uses the term "somatic," and makes clear that the claimed subject matter is somatic therapy. Support for this claim can also be found in the specification, for example, at pages 38-54, in which various somatic cells are exemplified.

New claim 77 is directed to mammalian cells. Support for this claim can be found in the specification, for example, at page 16, line 20, which uses the term "mammalian," and makes clear that the subject matter of the invention is mammalian tissue and cells. Support for this claim can also be found in the specification, for example, at pages 38-54, in which various mammalian cells are exemplified.

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New claim 78 is directed to ex vivo, somatic, mammalian cells. Support for this claim can be found in the specification, for example, at pages 38-54, which makes clear that the claimed cells are being introduced ex vivo. More specifically, pages 48-51 disclose preparations of various cell lines, as currently claimed. These described preparations (e.g., heparanase added to BMSC cells, as described at page 48, lines 19-22) are clearly done ex vivo. Support for this claim can also be found in the specification, for example, at page 35, line 8, which uses the term "somatic," and makes clear that the claimed subject matter is somatic therapy. Support for this claim can also be found in the specification, for example, at pages 38-54, in which various somatic cells are exemplified. Support for this claim can also be found in the specification, for example, at page 16, line 20, which uses the term "mammalian," and makes clear that the subject matter of the invention is mammalian tissue and cells. Support for this claim can also be found in the specification, for example, at pages 38-54, in which various mammalian cells are exemplified.

Finally, new claim 79 is merely claim 74, as currently amended, but written in independent form and new claim 80 is similar but without reciting the limitation of heparanase being added and without reciting to genetically modified cells. Because the amended and new claims are fully supported by the specification, no issue of new matter arises.

## **II. Regarding the written description rejection.**

Claims 71 and 74 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection.

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**A. Regarding the phrase "none of said somatic mammalian cells in said preparation is genetically modified to express heparanase."**

As stated in the previous response, the examples in the subject application describe a cell preparation to which heparanase is added. See, for example, Application at pages 48, lines 18-22, which describes adding heparanase to a preparation of bone marrow stromal cells. In view of this disclosure, the skilled artisan reading the application would necessarily know that such exemplified cells have not been genetically modified to express heparanase. Seeing from the disclosure in the specification that heparanase is being added to a cell preparation, there would be no reason whatsoever to genetically engineer the cells to express heparanase. The skilled artisan would clearly understand this.

The MPEP provides that the disclosure to support a claim can be implicit or inherent. MPEP §2163(I)(B). Moreover, the Examiner has the burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. §2163(II)(A).

Reading the subject application, the skilled artisan would clearly know that it implicitly describes cells that are not genetically modified to express heparanase. Therefore, claim 71 is adequately supported by the written description of the application. Furthermore, the Examiner has still not provided reasoning or an explanation why this implicit disclosure would not be adequate to the skilled artisan and, therefore, has not met his burden.

In other words, by reading that heparanase is being added, the skilled artisan would necessarily understand that the exemplified cells are not genetically modified to express heparanase. If the Examiner feels that the skilled artisan would not necessarily understand this, he must explain why. If the Examiner cannot explain why, he has not met his burden.

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In the present Office Action the Examiner states "while it is appreciated that applicants do describe species and examples of encompassed biological preparations that are not necessarily genetically modified cells, applicants do not have support for the **negative limitation** that none of said cells is genetically modified."

With great respect to the Examiner, he is entirely missing the point. The point is not the particular species and examples of cells described (which may or may not be genetically modified). Rather, the point is the disclosure in the subject application that heparanase is being added to the cell preparations. To the skilled artisan this would necessarily mean that the cells are not genetically modified to over-express heparanase. For if they were so modified, why would heparanase be added?

The Action goes on to say that "under applicants' logic, applicants could attempt to describe any of a number of limitations that were inherent to the disclosed examples, to carve out a claimed subgenus of biological preparations." However, this allegation is not true.

Applicant's argument is not based on the inherent nature of the exemplified cells. Rather, Applicant's argument is based on the context of the disclosure (of adding heparanase, as discussed above), which necessarily implies that the exemplified cells are not genetically modified to express heparanase.

Moreover, while he seems to acknowledge the concept of implied disclosure, the Examiner is really just giving lip service to it. For under the Examiner's logic, no amount to implied disclosure would be adequate support for a negative limitation. What is the legal basis of the Examiner's apparent belief?

To reiterate Applicant's position, there is no logical reason to genetically engineer cells to over-express heparanase when heparanase is already being added to this preparation of cells. This is an absolutely clear example of implied or inherent

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disclosure and, therefore, meets the requirements of written description under the law. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

**B. Regarding the terms "ex vivo," "somatic" and "mammalian."**

The Office Action alleges that these terms are not supported by the specification.

It is first noted that claim 73 (and, by dependency, claim 74) has been amended by deleting these terms. It is further noted that new claim 79 also does not contain any of these terms but, rather, is claim 74 written in independent form. Finally, new claim 80 also does not recite any of these terms.

Turning to the remaining claims, new claim 75 is directed to ex vivo cells. Support for this claim can be found in the specification, for example, at pages 38-54, which makes clear that the claimed cells are being introduced ex vivo. More specifically, pages 48-51 discloses preparations of various cell lines, as currently claimed. These described preparations (e.g., heparanase added to BMSC cells, as described at page 48, lines 19-22) are clearly done ex vivo. Once again, this disclosure is implicit (and is not a negative limitation). The skilled artisan reading these examples would clearly understand that the exemplified cell preparations are ex vivo.

New claim 76 is directed to somatic cells. Support for this claim can be found in the specification, for example, at page 35, line 8, which uses the term "somatic," and makes clear that the claimed subject matter is somatic therapy. Support for this claim can also be found in the specification, for example, at pages 38-54, in which various somatic cells are exemplified.

Finally, new claim 77 is directed to mammalian cells. Support for this claim can be found in the specification, for example, at page 16, line 20, which uses the term "mammalian," and makes clear that the subject matter of the invention is mammalian

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tissue and cells. Support for this claim can also be found in the specification, for example, at pages 38-54, in which various mammalian cells are exemplified.

Because the claims as amended are clearly supported by the specification, Applicant respectfully requests that this rejection be withdrawn.

### CONCLUSION

All of the issues raised in the Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore, Applicant respectfully requests a Notice of Allowance to this effect.

Respectfully submitted,



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Date: December 11, 2005

**Encl.:**

1. Request for Two-Month Extension of Time
2. Additional Claim Fee